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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,231	04/09/2002	Marie-Marthe Suncr	SYN-126	5862

22847 7590 06/28/2004

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EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,231	Applicant(s) SUNER ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 23 March 2004 has been entered in full. Claims 1-7 and 26-29 are amended. Claims 8-25 are cancelled.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7 and 26-29, drawn to the use of an erythroid cell in an assay in the reply filed on 23 March 2004 is acknowledged.

Claims 1-7 and 26-29 are under consideration in the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 27 January 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required. The post office address may be provided on either on an application data sheet or supplemental oath or declaration.

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Specification

2. The abstract of the disclosure is objected to because the legal term “said” is used.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

Correction is required. See MPEP § 608.01(b).

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: “A METHOD OF DETECTING THE INTERACTION OF A HETEROLOGOUS PROTEIN WITH A SIGNALING CASCADE OF AN ERYTHROID CELL”.

Claim Objections

4. Claim 28 is objected to because of the following informalities:

4a. In claim 28, line 2, there is a word missing after the word “enhancer”. (Please note that this issue could be overcome by amending the claim to recite “...which further comprises an enhancer that increases expression...”).

Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 5 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claim reads on a product of nature in that the claimed erythroid cell is not “isolated”. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S.

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303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified” as taught by page 13 of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-7 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 26-29 are directed to a method for detecting the interaction of a heterologous protein with an endogenous signaling cascade of an erythroid cell comprising conducting an assay to detect said protein interaction, wherein said erythroid cell is substantially undifferentiated, but which is capable of expressing a heterologous protein under the control of a globin promoter thereof. The claims also recite that the erythroid cell is a MEL cell, REL cell, or HEL cell. The claims recite that the globin promoter is the β -globin promoter. The claims recite an erythroid cell which is substantially undifferentiated but which is capable of expressing proteins under the control of a globin promoter. The claims recite that the erythroid cell comprises a cell as deposited at the European Collection of Cell Cultures under Accession No. 99012801. The claims recite a method of producing the erythroid cell which comprises maintaining and growing uninduced erythroid cells in culture. The claims also recite that the cell

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is transformed with a vector comprising a sequence which encodes a non-mammalian protein receptor under the control of a globin promoter associated with a cloning site or reporter cassette containing a reporter gene. The claims recite that the cell further comprises an enhancer and that the enhancer is the LCR enhancer.

(A) Regarding claim 6, the invention appears to employ novel erythroid cells. Since the erythroid cells are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the cells are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the erythroid cells. The specification does not disclose a repeatable process to obtain the erythroid cells and it is not apparent if the cells are readily available to the public. It is noted that Applicant has deposited the erythroid cells (p. 4 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

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- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." At p. 4, the address of the depository is missing. The specification should be amended to include such, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

(B) Regarding claims 5,7, and 26-29, these claims would be enabled for the claimed invention wherein the erythroid cell is the deposited cell (e.g., deposited at the European Collection of Cell Cultures under Accession No. 99012801) *if* the deposit is perfected.

The specification teaches that "a particular type of cell which can form cells of the invention are subclones of the MEL C-88 cell line, an example of which was deposited at the European Collection of Cell Cultures under the Accession number 99012801, deposited on 28 January 1999. This clone has been designated 'MEL-C88L'. Cell lines of this type can be used

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in functional assays as illustrated hereinafter, since the cells retain nuclei which are lost or otherwise functionally silenced on terminal erythroid differentiation" (pg 4, lines 7-13). The specification of the instant application teaches that Murine erythroleukemia C88 cells are cultured in Dulbecco's modified Eagle's medium supplemented with 10% foetal bovine serum and 2mM glutamine at 37°C, under 10% CO₂ - 90% air. "Leaky" MEL cells, C88L, which allow low level uninduced expression of globin genes in undifferentiated cells, are generated by prolonged culture of the cells (several months) prior to transfection studies (pg 13, lines 27-32). The specification also discloses that the expression construct pEV3TyrLoc is introduced into leaky MEL-C88L cells by electroporation and after transfection, cells are diluted in culture medium to concentrations of about 10⁴, 10⁵ and 2 x 10⁵ cells per ml and 1 ml aliquots are transferred to each well of a 24-well tissue culture plate. Twenty four hours after the transfection, G418 is added to a concentration of 1 mg/ml in order to select for stable transfectants. Individual clones are picked or pooled to generate populations, 7 to 10 days after the addition of selective medium (pg 14, lines 1-18). However, the specification of the instant application does not disclose general methods of producing undifferentiated erythroid cells comprising maintaining and growing uninduced erythroid cells in culture for a sufficient period of time and isolating a subclone which expresses protein. A large quantity of experimentation would be required of one skilled in the art to determine the optimal culture conditions and necessary steps for expressing a protein in undifferentiated erythroid cells. The state of the art is such that in the conventional LCR/MEL system, heterologous receptor expression is obtained *after* DMSO-induced differentiation of the cells into mature red blood cells (Poels et al. Insect Molec Biol 10(6): 541-548, 2001). Therefore, without specific

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guidance, undue experimentation would be required by the skilled artisan to produce and maintain undifferentiated erythroid cells that express a protein. One skilled in the art would not be able to predict that standard art-recognized cell culturing techniques would be able to produce and maintain undifferentiated erythroid cells that express a protein. Also, the instant specification and Poels et al. indicate that the properties of the deposited cell are unexpected and have not been replicated.

(C) Regarding claims 1-4, these claims would be enabled for the following method if the deposit is perfected: a method of screening for agonists of a receptor protein comprising (a) transforming the deposited cell with a construct comprising a non-mammalian receptor under the control of a globin promoter and LCR (Locus Control Region) enhancer, (b) contacting the cell with a candidate agonist, (c) measuring Ca^{2+} or cAMP to determine if the receptor was activated, and (d) identifying agonists as those candidates that caused a change in Ca^{2+} or cAMP levels.

The specification teaches that the Locus Control Region/Murine Erythroleukemia cells (LCR/MEL) system is used to express and characterize the *Locusta migratoria* tyramine receptor (an insect G protein coupled receptor (pg 12-14). The specification also discloses that elevations in intracellular Ca^{2+} in response to stimulation with ligands of the receptor are measured (pg 15-16; Figures 3-4). Furthermore, the specification teaches that the effect of tyramine on cAMP levels of transformed and untransformed cells is studied (pg 17-18; Figures 5-6). The specification also teaches that the reporter construct p3XVIPhyg(P) is transformed into MEL-C88L cells and the cells are incubated in the presence and absence of forskolin (pg 21-22; Figures 8a-8b). However, the specification of the instant application does not teach any methods

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or working examples that detect the interaction of a heterologous protein with an endogenous signaling cascade of an undifferentiated erythroid cell by conducting any assay to detect said protein interaction. Undue experimentation would be required of the skilled artisan to identify the specific interaction between any heterologous protein and an endogenous signaling cascade of the cell. Undue experimentation would be required by the skilled artisan to produce and maintain undifferentiated erythroid cells that express a protein. One skilled in the art would not be able to predict that standard art-recognized cell culturing techniques would be able to produce and maintain undifferentiated erythroid cells that express a protein. There is also little or no guidance in the specification as to the identities of the heterologous protein, the endogenous signaling cascade, and the interaction that is to be detected in the claimed assay. Undue experimentation would be required of the skilled artisan to express any heterologous protein under the control of a globin promoter in an undifferentiated erythroid cell and conduct all possible assays to detect an interaction between the protein and all possible signaling cascades of the cell. Such experimentation is considered undue. According to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of the claim, then this great quantity of experimentation should be considered in the overall analysis". The experiments disclosed in the instant specification are unrelated to the claimed method, and are therefore not adequate guidance, but merely an invitation to the artisan to use the claimed invention as a starting point for further experimentation.

Due to the large quantity of experimentation necessary to produce and maintain undifferentiated erythroid cells that express a protein, to identify a heterologous protein, an endogenous signaling cascade, and the interaction between the protein and signaling cascade and to conduct all possible assays to detect the unidentified interaction, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the current state of the art (see Poels et al.), the unpredictability of producing an undifferentiated erythroid cell that expresses a protein under the control of a globin promoter, and the breadth of the claims which fail to recite limitations as to the specific erythroid cell and the production and maintenance of undifferentiated erythroid cells that express a protein as well as limitations as to the identity of the protein, signaling cascade, and specific assay utilized, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

9. Claims 1-7 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 26-29 are directed to a method for detecting the interaction of a heterologous protein with an endogenous signaling cascade of an erythroid cell comprising conducting an assay to detect said protein interaction, wherein said erythroid cell is substantially undifferentiated, but which is capable of expressing a heterologous protein under the control of a

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globin promoter thereof. The claims also recite that the erythroid cell is a MEL cell, REL cell, or HEL cell. The claims recite that the globin promoter is the β -globin promoter. The claims recite an erythroid cell which is substantially undifferentiated but which is capable of expressing proteins under the control of a globin promoter. The claims recite that the erythroid cell comprises a cell as deposited at the European Collection of Cell Cultures under Accession No. 99012801. The claims recite a method of producing the erythroid cell which comprises maintaining and growing uninduced erythroid cells in culture. The claims also recite that the cell is transformed with a vector comprising a sequence which encodes a non-mammalian protein receptor under the control of a globin promoter associated with a cloning site or reporter cassette containing a reporter gene. The claims recite that the cell further comprises an enhancer and that the enhancer is the LCR enhancer.

The specification of the instant specification teaches that “use can be made of the signalling pathways in the cell, such as those in which G-proteins are involved, where for example, globin promoters can drive the expression of heterologous proteins which normally functionally interact with a G-protein, in particular G-protein coupled receptor molecules (GPCR)” (pg 4, lines 13-16). The specification also teaches that cells of the invention can be used to express heterologous proteins, including human proteins and non-mammalian proteins, such as insect proteins. (pg 7, lines 4-6). However, the specification does not teach any specific heterologous proteins or endogenous signaling cascades of an erythroid cell. The brief description in the specification is not adequate written description of an entire genus of proteins and signaling cascades.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the protein or signaling cascade of the encompassed methods and product, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The protein or signaling cascade itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class.

Therefore, only a specific protein and a specific signaling cascade, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-7 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The term "interaction" in claims 1-4 is a relative term which renders the claims indefinite. The term "interaction" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, what interaction is occurring between a heterologous protein and an endogenous signaling cascade? Binding? Activation? Inactivation?

13. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the assay steps that detect the protein interaction with an endogenous signaling cascade.

14. The term "substantially undifferentiated" in claims 1-7 and 26-29 is a relative term which renders the claims indefinite. The term "substantially reduced binding" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Neither the specification nor the art provide unambiguous definitions for "substantially undifferentiated" and "undifferentiated". Therefore, the metes and bounds of the claims cannot be determined by one skilled in the art.

15. Claim 5 is rejected as being indefinite because it is not clear of the meaning of the phrase "which allow the method in accordance with claim 1".

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16. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the uninduced/undifferentiated erythroid cells are maintained and grown in culture. For example, what media is used? What temperature? What growth factors are/are not used? How much time cultured?

17. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 27 recites the broad recitation "a reporter gene", and the claim also recites "such as the β -galactosidase gene" which is the narrower statement of the range/limitation.

18. Claim 27 is rejected as being indefinite because it is not clear of the meaning of the phrase "susceptible to modulation by a signaling cascade *used in an assay*".

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Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Hollis et al. U.S. Patent 5,538,885 (β -globin expression systems)

LeBoulch et al. U.S. Patent 5,631,162 (B-globin/LCR)

Vannucchi et al. Br J Haematol. 99(3):500-508, 1997. (MEL cells)

Davies et al. J Pharmacol Toxicol Methods. 33(3):153-158, 1995. (MEL cells)

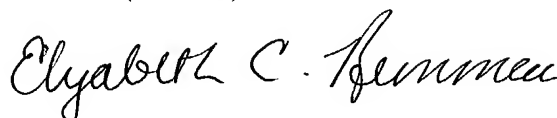
Amar et al. J Recept Signal Transduct Res. 15(1-4):71-79, 1995. (MEL cells)

Needham et al. Protein Exp Purification 6 : 124-131, 1995 (LCR/MEL cells)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BEB
Art Unit 1647
16 June 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER